

**National Cancer Institute
Institutional Review Board
AGENDA
November 17, 2014
10 CRC/3-1608**

- 1. Review of Draft Minutes, November 3, 2014**
- 2. Announcements**
- 3. Old Business**
- 4. New Business**
 - SOP 9 Continuing Review (Primary Reviewer System)
- 5. Problem Report Forms**
- 6. Other Expedited Actions**
- 7. Continuing Reviews**
- 8. Amendment** 14C0184-A, "Phase 1 Study of the Safety and Tolerability of ATR-101 in Adrenocortical Carcinoma" - Electron Kebebew, MD, PI
- 9. Amendment** 10C0066-E, "Collection of Human Samples to Study Hairy Cell and Other Leukemias and to Develop Recombinant Immunotoxins for Cancer Treatment" - Robert Kreitman, PI
- 10. Amendment** 14C0013-D, "A Phase I/II Trial of Ganetespib in Combination with the mTOR Inhibitor Sirolimus for Patients with Recurrent or Refractory Sarcomas including Unresectable or Metastatic Malignant Peripheral Nerve Sheath Tumors" - Brigitte Widemann, PI
- 11. Amendment** 12C0113-E, "A Phase I Study of a Continuous Intravenous Infusion of Recombinant Human Interleukin IL-15 (rhIL-15) in Adults with Metastatic Cancers"—Kevin Conlon, PI
- 12. Amendment** 13C0153-D, "A Phase II Trial of Enzalutamide in Combination with PSA-TRICOM in Patients with Non-metastatic Castration Sensitive Prostate Cancer"—Ravi Madan, PI
- 13. Initial Review** P131379, "A Phase 2 Pilot Study of BMN 673 (Talazoparib), an Oral PARP Inhibitor, in Patients with Deleterious BRCA1/2 Mutation-Associated Ovarian Cancer who have had prior PARP Inhibitor Treatment " - Jung-Min Lee, PI
- 14. Initial Review** P141751, "A Pilot Study of an Integrated Imaging Strategy to Phenotype Progression of HCC Tumors during and after Chemoembolization" - Elliot Levy, PI